K093025

510(k) SUMMARY (As Required per 21 CFR 807.92(c))

DEC 22 2009

GENERAL INFORMATION:

510k Owner's Name	Bovie Medical
Address	5115 Ulmerton Road Clearwater, Florida 33760
Contact Person	Richard A. Kozloff Vice-President; Quality Assurance/Regulatory Affairs Telephone #: (727) 803-8513 FAX Number: (727) 322-4665
Date Prepared:	September 25, 2009

DEVICE DESCRIPTION:

Trade Name:	Bovie Resistick™ II Coated Electrosurgical Electrodes
Common Name:	Electrosurgical Electrodes
Classification Name:	Electrosurgical Cutting and Coagulation Devices and Accessories (21CFR 878.4400; Class II; Product Code GEI)
Predicate Devices:	Resistick™ II Electrosurgical Electrode (K974735)

510(k) SUMMARY (As Required per 21 CFR 807.92(c))

INTENDED USE:

Bovie Resistick™ II Coated Electrosurgical Electrodes are used for cutting and coagulating soft tissues during open surgical procedures.

DEVICE COMPONENTS AND OPERATION:

Bovie Resistick II Electrosurgical Electrodes ("electrodes") consist of coated blade, needle, and ball configured electrodes, sold sterile and bulk non-sterile, and are designed for single-use. These electrodes are used in conjunction with an electrosurgical handpiece and generator to deliver RF energy used to cut and coagulate soft tissues during open surgical procedures. The intended use of these electrodes is the same as that of previously cleared Resistick II electrodes. The coating is designed to reduce friction and to minimize the buildup of burned tissue. Although the coating is chemically different from that of predicate devices, biocompatibility analyses are being performed to demonstrate safety.

Each electrode consists of a stainless steel shaft and tip, a coating, and an insulator. The insulation on the electrode meets the requirements for electrical safety testing of electrosurgical accessories.

Bovie Resistick II Electrosurgical Electrodes include three tip configurations; blade, needle, and ball. Within each configuration there are models that differ by length of the electrode shaft and whether the tips are partially exposed ("modified"). Eleven electrode configurations are the same shape and size as predicate devices cleared in premarket notification number K974735. There are an additional nine electrode configurations, each comprised of the same materials and having the same intended use. All electrodes are also to be available for sale as non-sterile components for subsequent placement into kits and trays.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Bovie Medical
% Mr. Richard Kozloff
5115 Ulmerton Road
Clearwater, Florida 33760

DEC 22 2009

Re: K093025
Trade/Device Name: Bovie Resistick™ II Coated Electrosurgical Electrodes
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: September 25, 2009
Received: September 29, 2009

Dear Mr. Kozloff:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: **Bovie Resistick™ II Coated Electrosurgical Electrodes**

Indications for Use:

Bovie Resistick™ II Coated Electrosurgical Electrodes are used for cutting and coagulating soft tissues during open surgical procedures.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

FOR M. MELKERSON

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K093025